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(54) Title: COLOR INDICATOR FOR DENTAL IMPRESSION MATERIAL

(57) **Abstract**

The invention relates to a dental impression composition and method of use thereof for taking impressions of the teeth amd gums and/or for the delivery of actives thereto; containing a color change indicator to signal when the temperature of the dental impression material is at the "warm impression" state, so that the impression composition is soft and malleable to conform to and engulf the teeth and gums. Further, the color indicator subsequently signals when the dental impression composition has cooled to a solid state and can be removed from the dentiture without deforming, so as to maintain an accurate impression.

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COLOR INDICATOR FOR DENTAL IMPRESSION MATERIAL

BACKGROUND OF THE INVENTION

1. Field of the Invention

The present invention relates to the a composition and method for the taking of dental impressions and the delivery of actives to the tooth and gum surfaces and more particularly, wherein a temperature indicator is present to signal when the dental impression material is at the proper temperature for application and removal.

2. The Prior Art

A variety of devices for making dental impressions of a patient's teeth are known. The term "dental impression" is used in the dental trade to designate a specific functional object and is distinguishable from the more general term "impression". Specifically, a dental impression provides a mold which is, in essence, an exact replica of the reverse image of a dental arch or arches or area of a dental arch. A dental impression is classified as full arch upper maxillary, full arch lower mandibular, antior, quadrant, or bite registration. Dental impression focuses on the precise size and position of the teeth, the gingival tissues, and any surgical alterations so that a working model may be produced. It is on this working model that a dental prosthetic device will be fabricated for eventual insertion into the mouth of a dental patient. Or, alternatively, the reverse image mold of the particular dental arch, or arches, or area of dental arch forms a well into which medicinal or hygiene agents can be held and when this mold is reapplied about the teeth and gums the agent is correspondingly so applied thereon.

Dental trays are one example of a dental impression device. Dental trays are receptacles used to carry a medicine or dental hygiene material, such as a bleaching agent or fluoride for application to the teeth and/or gums, or to provide within a malleable material carried therein an impression of the teeth and/or gums. The dental tray confines the particular malleable material next to the teeth and/or gums during the application or impression process.

U.S. Patent 5,616,027 discloses a dental tray system which includes a pliable resilient outer carrier tray and an inner tray both of thermoplastic material, the inner tray nests inside the outer carrier tray. The outer configuration of both trays adapt to fit over the upper or lower teeth. At a temperature range of 145° to 160° F, the thermoplastic material of which the inner tray is formed becomes pliable and moldable to readily take an impression of the teeth or gums, while the outer tray maintains its pliable resilient, supportive structure within this temperature range. To effect the heating the tray assembly is submerged into hot water or other suitable non-solvent liquid, so that the inner tray will substantially lose integrity of its shape and form during the heating process, while in the temperature range of 145° to 160° F, and will regain shape integrity when cooled to below of 145°F. A drawback to this method of customizing the dental tray to an individual patient's teeth is that there has been no practical means to identify when the material of the inner tray has reached 145° to 160° F and can be applied to the teeth or when it has sufficiently cooled so as to be removed from the teeth and still maintain an accurate impression.

U.S. Patent 5,503,552 discloses an extruded thermoplastic ethylene vinyl acetate copolymer usable for dental impressions. A device used to form a dental impression, of the copolymer, is placed into a container of hot water from 150° to 180° F for a period of from 30 to 300 seconds to soften the copolymer, prior to application into the mouth. The pre-form, after being heated, has a minimum time for removal from the mouth of less than 10 minutes. As in the case of U.S. Patent 5,616,027, a drawback is identifying when the pre-form has reached a temperature sufficient to soften it so as to accept the desired dental impression and subsequently when it has cooled sufficiently to be removed from the mouth while retaining the desired dental impression therein.

The prior art, U.S. Patents 5,596,025 and 4,788,240, disclose the use of color change indicators for establishing the cure point of certain silicone based polymeric systems, to signal when the mixture becomes "gelled" and has been cured irreversibly into a crosslinked polymer indicating that the setting process has been completed. U.S. 4,788,240 discloses a polyorganosiloxane composition, which can be obtained by adding anthraquinone dyes and/or azo dyes to a silicone elastomer composition which is cured by reaction of hydrosilyl radicals with alkenyl radicals bonded to silicon atoms, so that a change in color or fading out of color will occur as the cure thereof goes on. U.S. 5,596,025 discloses the use of a cure-indicating dye, which exhibits a color change in the presence of a silicon-bonded-hydrogen compound and a precious

metal hydrosilation catalyst. The particular color change indicators of U.S. Patents 5,596,025 and 4,788,240 exhibit only a single color change and are not helpful for indicating when the polymeric system has softened to accept the desired dental impression.

U.S. Patent 4,768,951 discloses a transparent thermoplastic dental tray containing a light-curing resin on the inside face thereof or containing a conventional impression-taking material cured by chemical reactions such as an alginate or rubber based material. U.S. 4,768,951 further discloses that the thermoplastic dental tray may contain for convenience, a temperature indicator, to change in color tone to indicate the softened state of the dental tray by heat. This single color change is not helpful for indicating when the light-curing resin on the inside face of the dental tray has hardened so as to be removed from the mouth without any distortion in the dental impression occurring.

Accordingly, there is a need in the art for an indicator of the warming of a dental impression material to be softened, so as to accept a dental impression, and the cooling of that dental impression material to allow removal from the mouth without any distortion of the dental impression therein.

SUMMARY OF THE INVENTION

In accordance with the present invention there is provided a dental impression composition of a thermoplastic polymer material and containing therein from about 2 to about 10% by weight of a thermal color indicator; which thermoplastic polymer material changes color at the warm impression temperature of the thermoplastic polymer composition to indicate that the thermoplastic polymer composition is soft and malleable and ready for application to the teeth, and which thermoplastic polymer composition upon cooling changes back to its original color, indicating the thermoplastic polymer composition has cooled to a solid state sufficient for removal from the teeth, while maintain an impression thereof.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

The thermoplastic impression materials of the present invention are heat softenable substances that are solid at temperatures of from about 100° F to about 120° F and below. Preferably they are free of objectionable taste or odor, and safe for use in the mouth. The malleable or softened ("warm impression") state is characterized by appreciable mass flow of the thermoplastic impression material under moderate (hand) pressure at some temperature between the from about 100° F to about 120° F (i.e. the warm impression transition temperature is from about 100°F to about 120°F) and the maximum temperature that can comfortably be withstood by oral tissues. This maximum temperature is generally thought to be about 170° F to about 180° F, although a maximum of about 150° F to about 160° F is preferred. The thermoplastic impression material should have sufficient warm impression fluidity and malleability to conform accurately to adult dentition and the gingival margin.

Useful thermoplastic impression materials of the present invention include polycaprolactones, which are aliphatic polyester elastomers; ethylene vinyl acetate copolymer (EVA) elastomers; styrene based plastics, such as polystyrene and its copolymers; acrylate based plastic, including polyacrylate and polymethacrylate resins; fluorine based plastics, such as polytetrafluoroethylene; polyvinyl fluoride, and polychlorotrifluorethylene; the diene based plastics, polybutadiene and its derivatives, and polyisoprene and its derivatives; urethane based plastics, such as polyurethane and its derivatives; and ethylenical based plastics, such as ethylene copolymers and their ionomer resins, and blends of these various resins, plastics and elastomers.

EVA copolymers are particularly useful in the practice of the present invention, and are commercially available as under the trade name designations: "Elvax" resins 40-W, 150, 220, 250, 260, and 350 from E.I. DuPont de Nemours & Co; "Ultrathene" EVA resins from Quantum Chemical Corp.; and "Escorene" EVA resins from Exxon Chemicals Co.

The ionomer resins of ethylene copolymers are preferred. Such ionomer resins may be obtained by the reaction of the base copolymers with metal ions capable of ionizing them. The base copolymers used may include ethylene/acrylic acid copolymers, ethylene/methacrylic acid copolymers, and ethylene/itaconic acid copolymers, and the metal ions to react with and ionize such base copolymers include Na^+ , and K^+.

A class of thermoplastic resin particularly useful in the present invention includes high molecular weight polycaprolactones, as well as, blends of high and low molecular weight polycaprolactones, referring to high molecular weight polycaprolactones as epsilon-caprolactone homopolymers or copolymers whose molecular weight is of the order of 20,000 or more, and low molecular weight polycaprolactones as having a molecular weight of less than about 10,000. Such polycaprolactones are available from Union Carbide Corporation, Danbury, Ct, 06817, such as under the tradename of PCL polycaprolactones. A preferred high molecular weight polycaprolactone, preferably used in combination with other resins, plastics and elastomers is an aliphatic polyester elastomer having a molecular weight of 40,000 to 80,000, available under the tradename of Capra 650, from Solvoy-Interox,

In order to enhance the physical properties of the thermoplastic impression composition of the present invention, fillers, plasticizers, stabilizers, and antioxidants may be added thereto. A preferred stabilizer is tris(2,4-di-tert-butylphenyl) phosphite. Preferred antioxidants include antioxidant tetrakis[methylene(3,5-di-tert-butyl 1,4-hydroxyhydrocinnamate)] methane and Ingraox 1010 and Igraphos 160, available from Ciba Geige. The total amount of additives should preferably be less than 70 weight % based on the total weight of the thermoplastic impression composition. With the additives used in an amount greater than about 70 weight %, no sufficient heat softening property may be obtained.

Usable as the fillers are calcium carbonate, molten powdery calcium, titanium dioxide, zirconium silicate, aluminum silicate, silica, M. M. A. polymers, vinyl chloride powders, alumina, glass, kaolin, anhydrous silicic acid, hydrous silicic and the like. A preferred silica filler is Hisil 233, available from PPG Industries. Useful natural plasticizers (e.g. oils) include castor oil, cottonseed oil, mineral oil, orange oil and peanut oil. Useful synthetic plasticizers (e.g. phthalate esters) include commercially available synthetic plasticizers such as dioctyl adipate, dioctyl sebacate, polyisobutylene, and phthalates and blends thereof.

It is also preferred that the thermoplastic impression composition having heat softening properties according to the present invention, also excel in the resistance to attack by chemicals such as alcohols, carbolic acid, chlorohexyzine and cationic soap etc., since they may be sterilized and cleaned by immersion in aqueous solutions thereof for repeated use.

An essential feature of the present invention is the addition of from about 2 to about 10% by weight of a thermal color change indicator to the thermoplastic polymer material (which is hard at room/ambient temperature), to provide a color change when the combined thermoplastic impression composition has been heated to a temperature sufficient to become softened and malleable for application to the dentition and supporting gums (i.e. the composition's warm impression state) and also to indicate when the thermoplastic impression composition has cooled to a rehardened state, to allow removal from the dentition and gums while maintain an accurate impression thereof. Identification of the precise point at which the thermoplastic impression composition reaches the desired warm impression state is not only important as a time saving feature; but, certain thermoplastic materials, such as polyvinyl acetate; tend to swell and become too soft when immersed in water too long.

U.S. Patent 4,717,710 discloses a thermal color change indicator disclosed to be useful in printing inks, coating and incorporated into waxes, soaps and synthetic resins, such as in the present invention, which when heated to a critical temperature will change from its original color to clear and which when subsequently cooled below the critical temperature will return to its original color. The thermal color change indicator is composed of (1) an electron-donating chromogenic material; (2) a 1,2,3-triazole compound; (3) a weakly basic, sparingly soluble aromethine or carboxylic acid primary amine salt; and (4) an alcohol, amide or ester serving as a solvent. The electron-donating chromogenic material is the color providing component and is from 0.1 to 20% by weight of the thermal color change indicator. Particular electron-donating chromogenic materials which may be used individually or in combination include substituted phenylmethanes and fluorans such as 3,3'-dimethoxyfluoran (yellow), 3-chloro-6-phenylaminofluoran (orange), Crystal Violet lactone (blue), Malachite Green lactone (green) and 3,3'-bis-(p-dimethylaminophenyl)phthalide (green).

The triazole compound component of the thermal color indicator is present in an amount of from 0.1 to 40% by weight of the thermal color change indicator and includes such compounds as 1,2,3-benzotriazole, 1,2,3-triazole ethyl 4-methyl-5-carboxylate, 4(5)-hydroxy-1,2,3-triazole and 5(6)-methyl-1,2,3-benzotriazole.

The azomethine or carboxylic acid primary amine salt component of the thermal color indicator is present in an amount of from 0.5 to 50% by weight of the thermal color change indicator. Useful azomethines include those having the following formula:

R-CH=N-R';

R-CH=N-R'-N-CH-R; and

R-N=HC-R'-CH=N-R

wherein, R and R' are each an aliphatic residue, substituted aliphatic residue, aromatic residue, substituted aromatic residue, heterocyclic residue or substituted amino group, wherein each of the formulae include one aromatic residue and one substituted aromatic residue.

Sparingly water soluble carboxylic acid primary amine salts useful in the thermal color change indicator are easily obtained by reacting a carboxylic acid with a primary amine and are represented by the following formula:

$R\text{-}(COOH)_x\text{-}R'\text{-}(NH_2)_y$

wherein R and R' are defined above, and x and y are each an integer. Examples of useful carboxylic acids include aliphatic carboxylic acids such as caprylic acid, capric acid, lauric acid, myristic acid and stearic acid. Examples of primary amines which are to be reacted with such carboxylic acids include aliphatic primary amines such as caprylamine, laurylamine, myristylamine, stearylamine and coconut amine.

Suitable solvents for use as the fourth component of the thermal color change indictor include alcohols, amides, or esters in an amount of 1 to 50% by weight of the color change indicator. The alcohols can be saturated monohydric alcohols including octyl alcohol, nonyl alcohol, and cetyl alcohol, as well as, unsaturated alcohols, which include geraniol, nerol, linalool and oleyl alcohol. The amides which are useful as solvents include acetamide, caprylic acid amide, lauric acid amide, myristic acid amide, stearic acid amide and benzimidazole. The esters which are useful as solvents include stearic acid glyceride, lanolin, diphenyl phthalate, lauric acid glyceride, and palmitic acid glyceride.

A particular thermal color change indicator useful in the present invention would include 4 parts of Crystal Violet lactone, 16 parts of 1,2,3-benzotriazole, 50 parts of myristyl alcohol and 30 parts of $C_6H_4CH=NC_6H_4(P\text{-}OCH_3)$, i.e. benzylidene p-anisidine. This particular thermal color change indicator will be appear blue at temperatures of about 140°F or less, and over about 140°F will become clear. When admixed with the thermoplastic impression materials of the present invention, which are generally white in color, the mixture will appear blue below about 140°F and white above about 140°F.

Commercially available thermal color indicators, compatible with the thermoplastic impression materials of the present invention and which provide the desired softening/hardening indication of the thermoplastic impression composition, at above 120° F, are available from Chroma Corporation, McHenry, Illinois, under the trade designations Chromacolor Type 60 PP-mauve and PP-light green. Chromacolor PP-light Green Type 60 is green at ambient room temperature and turns the white of the underlying thermoplastic impression composition above 120° F, remaining white to at least the maximum comfortable temperature of about 160° to about 180° F and returning to green upon cooling and Chromacolor PP-mauve Type 60 is purple at ambient room temperature, turning white at above 120° F, remaining white to at least the maximum comfortable temperature of about 160° F to about 180° F and returning to purple upon cooling. Chromacolor PP-mauve Type 60 is preferred, due to its more "striking" color change.

A preferred thermoplastic impression composition of the present invention is about 60% to about 70% by weight of polycaprolactone, such as Capra 650; about 5% to about 10% by weight of ethylene vinyl-acetate (EVA) co-polymer with a proportion of vinyl acetate being in the range of 24.3% to 25.7% by weight and a melt index between 17.3 and 20.9 decigrams/minute, such as Elvax 350 by DuPont; about 5% to about 20% styrene-butadiene-styrene or styrene butadiene copolymer, such as Stereon 840A by Firestone; about 10% to about 20% by weight of silica filler, such as Hisil 233 from PPG Industries; about 0.1% to about 3% by weight of a primary process stabilizer such as tris(2,4-di-tert-butylphenyl) phosphite; about 0.1% to about 3% by weight of an antioxidant tetrakis[methylene(3,5-di-tert-butyl 1,4-hydroxyhydrocinnamate)] methane and about 2% to about 10% of a thermal color change indicator, such as Chromacolor PP- mauve Type 60. A most preferred formulation is approximately 61.2% by weight polycaprolactone, such as Capra 650 by

Solvoy-Interox; approximately 6% by weight of ethylene vinylacetate co-polymer such as Elvax 350 by DuPont; approximately 9% by weight polystyrene butadiene co-polymer, such as Stereon 840A by Firestone; approximately 14% by weight of silica filler, such as Hisil 233; approximately 0.2% by weight of a primary antioxidant, such as Ingraox 1010 and approximately 0.2% by weight of a secondary antioxidant such as Igraphos 168, to which is added about 3% thermal color change indicator Chromacolor PP-mauve Type 60 from Chroma Corporation.

The thermoplastic impression composition, containing the requisite thermal color indicator of the present invention, can be extruded, molded, or otherwise formed under heat and pressure into sheets, strips, rods, or bars. The formed thermoplastic impression composition can be supported by a dental tray or directly applied to the dental arch or portion thereof. The formed thermoplastic impression composition, with or without a supporting dental tray, can be immersed in a container of hot water or other suitable non-solvent liquid, so as to cause the thermoplastic impression composition to raise in temperature and become sufficiently malleable and pliable to conform easily to the patient's teeth and gums, as indicated by a color change of the thermoplastic impression composition. As soon as practical after this indicative color change, the thermoplastic impression composition should be applied, by hand, into the patient's mouth, so that the thermoplastic impression composition molds itself on and about the patient's teeth and gums. The thermoplastic impression composition is allowed to remain on and about the tooth and gum for sufficient time to cool sufficiently to maintain that impression, the thermoplastic impression composition is removed from the mouth, as indicated by the color change indicator changing back to its original color.

U.S. Patent 5,616,027 discloses the application of a thin, 0.01 to 0.05 mm, silicone-based elastomer sheet as a blocker to cover the teeth and gums, usable to separate the tooth surfaces and gums from the thermoplastic impression composition molded thereon. This thin silicone-based elastomer is sandwiched between the teeth surfaces and the thermoplastic impression composition, usually by being placed on the exterior thermoplastic impression composition when it is first forced onto and about the teeth and gums. This thin silicone-based elastomer is subsequently removed from between the inner tray and the teeth and gums, causing the impression within the inner tray to be 0.01 to 0.05 mm larger than the teeth and gums themselves (depending upon the exact width of the elastomer sheet). This 0.01 to 0.05 mm separation allows enough space to facilitate easy removal of the thermoplastic impression composition

from irregular tooth surfaces, such as undercuts or edges of fillings, and space so that when applying the medicinal and hygiene agents to the inner surface of the inner tray, after the tooth impression has been made therein, and repositioning the inner tray over the teeth and gums, there is adequate separation for the medicinal or hygiene agent. Alternatively, the therapeutic agent can be formulated into the thermoplastic impression composition as an ingredient therein and the agent can then be applied in the initial molding of the thermoplastic impression composition onto and about the tooth and gums.

The ingredients of the thermoplastic impression composition can be blended by hand or by mechanical mixing. The ingredients preferably are warmed sufficiently to melt the thermoplastic portion, but if desired can be mixed at lower temperatures. Any suitable mixing device can be used, including kettles equipped with mechanical stirrer, extruders, rubber mills, and the like. After processing and forming, the thermoplastic impression composition can be sold unwrapped, loosely wrapped in a package, or packaged in tubes, syringes, flexible outer plastic skins, plastic or metal trays, or the like.

As stated, various medicinal and/or hygiene agents can be applied to the teeth or gums by being sandwiched into the interface between the thermoplastic impression composition and the teeth and gums, or by formulated an effective amount of such agent into the thermoplastic impression composition itself. Useful medicinal and hygiene agents include, antibacterial agents, such as triclosan; bleaching or whitening agents, such as peroxide; anticavity agents, such as fluoride gel; desensitizing agents, such as potassium nitrate; and the like.

The following example is further illustrative of the nature of the present invention, but it is understood that the invention is not limited thereto. All amounts and proportions referred to herein and in the appended claims are by weight, unless otherwise indicated.

EXAMPLE

A dual dental tray system was prepared having a clear plastic outer supporting tray adapted to fit over the upper or lower teeth and nested therein, as the inner tray, a thermoplastic impression composition of the present invention, designated Sample 1, which reaches its warm impression state at over 120° F. The inner tray was formed by standard compression molding, a technique well known in the art, into the U-shaped cross-section and overall horseshoe shaped configuration which is the general channel profile of inner dental trays. The formulation used for the thermoplastic impression composition of Sample 1 is presented in Table I, below:

Table I

Formulation of Sample 1

Ingredient	% by Weight
Chromacolor PP-mauve Type 60	3.0
Ethylene Vinyl-acetate (EVA)	6.27
Polycaprolactone	61.18
Polystyrene-butadiene styrene	9.27
Silica	13.9
Tris(s,4-di-tert-butylphenyl) phosphite	0.19
Tetrakis[methylene(3,5-di-tert-butyl 1,4-hydroxyhydrocinnamate)] methane	0.19

To test the thermal color change properties of Sample 1, it was suspended in a clear beaker of water, whose lower portion was encased in an electric heating mantle. As the temperature of the water was raised and subsequently lowered, the color of the Sample 1 was observed and recorded at the critical temperatures of approximately 72° F (ambient, room temperature), 120° F, 160° F, and 180° F; the recorded data is reproduced in Table II, below.

A series of comparative inner trays were formulated, containing other EVA compatible, thermal color change indicators from Chroma Corporation, designated Samples 2 through 14; using the formulation of Table I; except, that the Chromacolor PP-mauve Type 60 color change indicator was replaced by an equal amount of the

comparative thermal color change indicator. The procedure of Example I was repeated using Samples 2 through 14 and the results therefrom are also recorded in Table II, below.

Table II

Observed Color at Critical Temperatures

Sample #	Color Change Indicator	Ambient	120° F	160° F	180° F
Sample 1	Chromacolor PP-Mauve Type 60	Purple	Purple	White	White
Sample 2	Chroma Target 1	Dark Blue	Light Blue	Light Blue	Light Blue
Sample 3	Chroma Target 2	Light Blue	White	White	White
Sample 4	Chroma Target 3	Purple	Light Purple	Light Purple	Light Purple
Sample 5	Chroma Target 4	Burgundy	Redish	Redish	Redish
Sample 6	Chroma Target 5	Bright Pink	Fuchsia	Fuchsia	Fuchsia
Sample 7	Chroma Target 6	Pink	White	White	White
Sample 8	Chroma Target 7	Teal	Teal	Teal	Teal
Sample 9	Chroma Target 8	Bright Pink	Lighter Bright Pink	Lighter Bright Pink	Lighter Bright Pink
Sample 10	Chroma Target 9	Teal	Teal	Teal	Teal
Sample 11	Chroma Target 10	Teal	Teal	Teal	Teal
Sample 12	Chroma Target 11	Orange	Yellow	Yellow	Yellow
Sample 13	Chroma Color PP - E-1 Orange Type 25	Orange/Rust	Bright Yellow	Bright Yellow	Bright Yellow
Sample 14	Chroma Color PP - C-0 Red Type 27	Red/Orange	Very Light Pink	Very Light Pink	Very Light Pink/White

The data recorded in Table II shows only in the case of Sample 1 did the color change indicate the critical warm impression temperature of over 120° F, at which the thermoplastic impression composition becomes ready for application to the teeth and gums. Comparable satisfactory observations were also made with Chromacolor PP-light green Type 60, which was green at ambient, green at 120° F, white above 120° F and remained white at from 160° to 180° F and returned to green upon cooling to under 120° F.

CLAIMS

1. A dental impression composition comprising a thermoplastic impression material and from about 2 to about 10% by weight of a thermal color change indicator, where when the temperature of the composition is raised above the composition's warm impression state, the composition changes color and where upon cooling the composition below the compositions warm impression state, it changes color back to its original color.

2. The dental impression composition of claim 1, wherein the dental impression composition is in the form of an inner tray of a dual dental tray system.

3. The dental impression composition of claim 1, wherein the temperature of the warm impression state of the dental impression composition is over 120° F.

4. The dental impression composition of claim 1, wherein the dental impression composition contains a filler, or an antioxidant, or a stabilizer or combination thereof.

5. The dental impression composition of claim 1, wherein the dental impression material is comprised of polycaprolactone, ethylene vinyl-acetate, styrene-butadiene-styrene, silica, tris(s,4-di-tert-butylphenyl) phosphite, and tetrakis[methylene(3,5-di-tert-butyl 1,4-hydroxyhydrocinnamate)] methane.

6. A dental impression composition comprising a thermoplastic impression material and from about 2 to about 10% by weight of a thermal color change indicator in the form of sheets, strips, rods, or bars; whereupon when the temperature of the composition is raised above the compositions warm impression state, the composition changes color, and upon cooling the composition below the compositions warm impression state changes color back to its original color.

7. A method for taking of dental impressions of the teeth and gums, comprising:

   a) formulating a dental impression composition having a warm impression transition temperature of over 120°F, containing a thermoplastic impression material and from about 2 to about 10% by weight of a thermal color change indicator;

b) applying heat to the dental impression composition, until the dental impression composition reaches a temperature of over 120° F, as indicated by the color change indicator contained therein changing color;

c) applying by hand the dental impression composition into the patients mouth, so that the thermoplastic impression composition molds itself on and about the patient's teeth and gums;

d) allowing the dental impression composition to remain about the patient's teeth and gums until the dental impression composition .cools to a temperature of less than 120° F, as indicated by the thermal color change indicator contained within the dental impression composition changing back to its original color; and

e) removing the dental impression composition from the patient's teeth and gums.

8. A method for the application of medicinal or hygiene agents to the teeth and gums, comprising:

a) formulating a dental impression composition having a warm impression transition temperature of over 120°F, containing a thermoplastic impression material, from about 2 to about 10% by weight of a thermal color change indicator, and an effective amount of a antibacterial, bleaching, whitening, anticavity, or desensitizing agent;

b) applying heat to the dental impression composition, until the dental impression composition reaches a temperature of over 120° F, as indicated by the color change indicator contained therein changing color;

c) applying by hand the dental impression composition into the patients mouth, so that the thermoplastic impression composition molds itself on and about the patient's teeth and gums;

d) allowing the dental impression composition to remain about the patient's teeth and gums until the medicinal or hygiene agent has transferred to the oral surface; and

e) removing the dental impression composition from the patient's mouth.

9. A method for the application of medicinal or hygiene agents to the teeth and gums, comprising:

a) formulating a dental impression composition having a warm impression transition temperature of over 120°F, containing a thermoplastic impression material, and from about 3 to about 10% by weight of a thermal color change

indicator;

b) applying heat to the dental impression composition, until the dental impression composition reaches a temperature of over 120° F, as indicated by the color change indicator contained therein changing color;

c) applying by hand the dental impression composition into the patients mouth, so that the thermoplastic impression composition molds itself on and about the patient's teeth and gums;

d) removing the dental impression composition from the patient's teeth and gums, so that a reverse impression of the patients teeth is contained therein;

e) applying to the surface of the reverse impression of the patients teeth a medicinal or hygiene agent;

f) reapplying the dental impression composition to the patients teeth, so that the teeth and gums fit within the reverse impression within the dental composition and so that the medicinal or hygiene agent within the reverse impression is applied to the tooth and gum surfaces to provide treatment thereon;

g) allowing the dental impression composition to remain about the patient's teeth and gums until the medicinal or hygiene agent has transferred to the oral surface; and

h) removing the dental impression composition from the patient's mouth.

10. The method according to claim 9, wherein the medicinal or hygiene agent is either an antibacterial, a tooth whitening, an anticavity fluoride gel, or a desensitizing agent.

11. The method according to claim 7, wherein a silicone-based elastomer sheet from 0.01 to 0.05 mm in thickness is applied over the teeth and gums prior to or simultaneously with the application of the dental impression composition to the teeth and gums, whereby the application and removal of the dental impression composition to the teeth and gums is facilitated.

12. The method according to claims 8 or 9, wherein a silicone-based elastomer sheet from 0.01 to 0.05 mm in thickness is applied over the teeth and gums prior to or simultaneously with the application of the dental impression composition to the teeth and gums, whereby the application and removal of the dental impression composition to the teeth and gums is facilitated, as is the application to the teeth and gums of medicinal or hygiene agents.